UNIVERSITY OF CALIFORNIA, IRVINE
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Energy based devices for the improvement of skin and skin appendages

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

RESEARCH TEAM
Lead Researcher
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STUDY LOCATION(S):
UC Irvine Main Campus – Hewitt Hall, Gottschalk Medical Plaza, Beckman Laser Institute

STUDY SPONSOR(S):
University of California, Irvine, Department of Dermatology

WHY IS THIS RESEARCH STUDY BEING DONE?
The purpose of this research study is to compare and contrast multiple energy-based devices for rejuvenation of the scalp, face, neck/décolletage, hands, upper and lower extremities, trunk and/or vagina regarding their efficacy and side effect profile.

Non-ablative devices that do not remove the top layer of skin and ablative devices that remove the top layer of skin are the most commonly used minimally-invasive treatments for improvement of skin and skin appendages (i.e hair follicles) which includes multiple measures such as correction of pigment, treatment of benign lesions associated with sun damage, and rebuilding the underlying architecture of the skin. After injury by varying methods (including laser, radiofrequency or electrocoagulation), these devices allow for the new production of proteins such as collagen and elastin which may result in better skin tone and decreased wrinkles. Additionally, lasers can reduce inflammation within the skin and skin appendages which promotes hair growth. Current devices on the market for rejuvenation include the lasers such as the Fraxel, the Halo, the Helios III, the Pico, the Vbeam, the ThermiVa, the DiVa, and PALLAS which have all been shown to have efficacy for the improvement of the scalp, face, décolletage, trunk, hands and/or vagina. In this study we propose to compare the efficacy and side effect profile of these devices for improvement of the skin of various areas of the body including the scalp, face, décolletage, hands, trunk, upper and lower extremities, and vagina.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 150 participants will take part in the research at UCI.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
Please note this may not be a complete list of eligibility criteria. We have included a few examples of study criteria to help you better understand how your eligibility in the study will be determined; your study team will go through the study eligibility criteria with you to verify if you qualify for participation in this study.

Inclusion Requirements
You can participate in this study if you are at least 18 years of age or older, are male or female, are of any skin type, and exhibit signs of aging or inflammation.

Exclusion Requirements
You cannot participate in this study if you are less than 18 years of age, are taking medications that may affect blood coagulation, have a known history of blood coagulopathies/clotting disorders, have a known history of a disease that may compromise the local blood supply, implanted medical devices, or previously received energy-based rejuvenation in the treated area 3 months prior to study enrollment.

HOW LONG WILL THE STUDY GO ON?
This study includes 5 to 6 visits and takes about seven hours over a period of 6 months for all laser treatments except for PALLAS treatment. Subjects who receive treatment with the PALLAS laser will receive biweekly treatments for a total of 25 visits (including one month follow-up), and takes about 13 hours over 6 months.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY?
Before you can participate in the main part of the study...
You will need to have "screening" exams, tests or procedures. The screening process helps the researchers decide if you meet the study requirements listed below. The screening procedures include documentation of your prior medical history and treatments, concomitant medications and vital signs.

During the main part of the study...
If the screening exams, tests and/or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following procedures and tests done. The main study tests and procedures include…

a. Energy-based rejuvenation procedure using either the Fraxel, Halo, Helios III, Vbeam, or PicoWay for the face, neck/décolletage, hands, upper and lower extremities and/or trunk OR the ThermiVa or DiVa for the vagina OR PALLAS for scalp or hypopigmentation disorders. Your initial study visit, including treatment, should last approximately 1.5 to 2 hours.
b. Local anesthesia may be used before treatment if you and the physician agree (such as before Fraxel treatment).
c. For all laser treatments, you will be required to wear eye protection that will be supplied by the office.
d. Evaluation of side effects using a patient diary and physician-reported adverse events during follow-up visits.
e. Continued documentation of medical history and concomitant medications throughout the study period.
f. Photographs will be taken to monitor your progress.
g. Physician and patient assessments and questionnaires.
h. If you agree to participate, multi-photon microscopy (MPM) will be completed at Visit 1, 2, 3 and 5 (Day 1, 14, 30 and 90). Multi-photon microscopy is a non-invasive imaging modality. A metal disc with a central opening will be placed on the area that will receive treatment; the microscope head is attached magnetically to the metal disc and rests on your body. You will be asked to sit very still and a laser will be used to capture the MPM image. The entire procedure should take no longer than 15 minutes and there is no discomfort involved. The same procedure will be repeated four times throughout this study.

Procedure	**Visit 1 (D1+/-3 days)***	**Visit 2 (D14+/- 3 days)**	**Visit 3 (D30+/- 3 days)**	**Visit 4 (D60+/- 3 days)**	**Visit 5 (D90+/-3 days)**
Energy-based device Treatment (Fraxel, Halo, Helios III, PicoWay, Vbeam, ThermiVa, or DiVa)	**X**				
Vitals (Temperature, blood pressure, heart rate, respiratory rate)	**X**				
Prior Medical History and Treatments	**X**				
Concomitant Medications	**X**	**X**	**X**	**X**	**X**
Adverse Events	**X**	**X**	**X**	**X**	**X**
Physician and Patient Assessments	**X**	**X**	**X**	**X**	**X**
MPM Imaging (Optional)	**X**	**X**	**X**		**X**

Procedure	**Visit 1* (D1+/-3 days)**	**Visits 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23 (biweekly, ≥ 1 day between)**	**Visit 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24 (biweekly, ≥ 1 day between)**	**Visit 25 (D90+/-3 days)**
Treatment (PALLAS)	**X**	**X**	**X**	
Safety Assessments				
Vitals (Temperature, blood pressure, heart rate, respiratory rate)	**X**	**X**	**X**	
Prior Medical History and Treatments	**X**			
Concomitant Medications	**X**		**X**	**X**
Adverse Events	**X**	**X**	**X**	**X**
Physician and Patient Assessments	**X**		**X**	**X**
MPM Imaging (Optional)	**X**		**X**	**X**

After you complete the main part of the study…

Follow-up visits will occur at 14 days, 30 days, 60 days and 90 days for Fraxel, Halo, Helios III, PicoWay, Vbeam, ThermiVa, or DiVa or 30 days after completion of the treatment period for PALLAS and will last no longer than 30 minutes. At follow-up visits the physicians will ask about your current medications and any adverse events that may have occurred post-treatment. In addition:

a. Photographs will be taken to monitor your progress.
b. Optional imaging using the multi-photon microscopy may also be completed if you consented for these images to be taken.
c. Physician and patient assessments and questionnaires.

WHAT ARE THE POSSIBLE SIDE EFFECTS OR RISKS RELATED TO THE STUDY?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. The researchers may give you medicines to help lessen side effects. Many side effects go away soon after the procedure is completed. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to the research team about any side effects you experience while taking part in the study.

Risks and side effects related to the energy-based rejuvenation devices are related to standard of care procedures. The only study related risk is breach of confidentiality.

Psychological discomforts: Questionnaires used in this study may cause embarrassment or anxiety, or the questions the researchers ask you may be upsetting or make you uncomfortable. If you do not wish to answer a question, you can skip it and go to the next question.

ARE THERE BENEFITS TO PARTICIPATING IN THIS STUDY?

Participant Benefits

Taking part in this study may or may not make your health better. These energy-based rejuvenation modalities may result in improvement in wrinkles, skin laxity, pigmentary changes, and skin and skin appendage inflammation.

Benefits to Others or Society

This study will help researchers learn more about energy-based treatment modalities and techniques, and it is hoped that this information will help in the treatment of future patients with skin changes.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to participate, or if you withdraw from this study before it is completed, your other choices may include:

- Getting no treatment
- Getting standard treatment for your condition without being in a study.
- Getting a different experimental treatment/taking part in another study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

Compensation

You will not be compensated for your participation in this research study.

Reimbursement

You will not be reimbursed for any out of pocket expenses, such as parking or transportation fees.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

The University of California, Irvine will supply the Fraxel, Halo, Helios III, PALLAS, Picoway, Vbeam, ThermiVa and DiVa machines at no cost while you take part in the study. However, there are out-of-pocket expenses such as discounted payment for the rejuvenation treatment (such as device tip, disposable materials, physician time and clinic overhead), parking and transportation fees. You and /or your health plan/insurance will be billed for the costs of any routine medical care you receive to diagnose and/or treat any medical condition(s) within the scope of this study. You and /or your health plan/insurance will need to pay for this routine care. You will also be responsible for any co-payments or deductibles required by your insurance. Some health plans/insurance companies will not pay the costs associated with these tests, procedures, and/or drugs. Financial counseling and itemized cost estimates are available upon request.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study, you should notify the research team immediately**. The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, the study sponsor decides to stop the study or your safety and welfare are at risk.

If you experience any of the side effects listed above, if your health worsens, or if you are injured during the research, you may need to be withdrawn from the study, even if you would like to continue. The research team will make this decision and let you know if it is not possible for you to continue. The decision may be made to protect your safety and welfare, or because the research plan does not allow people who develop certain conditions to continue to participate.

If you withdraw or are removed from the study, the researcher may ask you to return for a final close-out visit and evaluation.

If you elect to withdraw or are withdrawn from this FDA-regulated research study, the data collected from your participation in this study must remain in the trial database in order for the study to be scientifically valid.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT?
Subject Identifiable Data
Some identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. Personal identifiers will remain so that during the study period, follow-up appointments can be made.

Data Storage
Research data will be maintained in paper format in a secure location at UCI. Only authorized individuals will have access to it.

Research data will be stored electronically on a secure computer in an encrypted file with password protection.

Data Retention
The researchers intend to keep the research data for approximately 6 years. The researchers intend to keep identifying photographs until the research is published and/or presented.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

Any information derived from this research project that personally identifies you will not be released or disclosed by these entities without your separate written consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations resulting from this study will not include identifiable information about you.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

ClinicalTrials.gov is a Web site that provides information about clinical trials. A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Investigator Financial Conflict of Interest
No one on the study team has a disclosable financial interest related to this research project.

1. I agree that photographs of my treated area may be taken. I understand that some of these photographs may contain identifiable information and that all efforts will be made to remove this identifiable information before publication or presentation.

YES	NO

So long as your specimens remain identifiable, you are free to withdraw the use of your specimens kept for future research. If you decide to withdraw your specimens from such use, you should notify the research team immediately. Specimens previously provided to researchers and any data generated will continue to be used.

2. I agree to participate in multi-photon microscopy (MPM) imaging of my treated area. These MPM images will not be identifiable.

YES	NO

3. UCI researchers may contact me in the future to ask me to take part in other research studies.

YES	NO

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

A 24-hour number is also listed on the top of this form to report any health concerns or unanticipated problems you may experience after normal hours or on weekends.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any suggestions, problems or concerns you may have about the study, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at IRB@research.uci.edu or at 141 Innovation Drive, Suite 250, Irvine, CA 92697.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human subjects involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.

I agree to participate in the study.

Subject Signature	**Date**
Printed Name of Subject	
Signature of Person Obtaining Informed Consent	**Date**
Printed Name of Person Obtaining Informed Consent	

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive research procedures).

Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

For the witness:
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
Witness Signature **Date**
(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday – Friday, 8 am – 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 141 Innovation Drive, Suite 250, Irvine, CA 92697.